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TITLE: Exercise to Counteract Loss of Bone and Muscle During
Androgen Deprivation Therapy in Men with Prostate Cancer

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The objective is to determine whether a 1-year intensive resistance exercise training (RT) program is more effective than a moderate-intensity walking program in ameliorating the effects on body composition of androgen deprivation therapy (ADT). It is postulated that, in men on ADT for the treatment of locally advanced prostate cancer: 1) RT will attenuate the declines in bone mineral density (BMD) and fat-free mass (FFM) to a greater extent than walking; and 2) both RT and walking will prevent an increase in fat mass. Primary outcomes are lumbar spine BMD and FFM. Secondary outcomes are: total body and hip BMD; fat mass; markers of bone turnover; serum sex hormones; physical functional performance; and quality of life. Local project support will enable assessment of risk factors for cardiovascular disease (blood lipids, glucose tolerance, arterial stiffness). Communications with the Army HSRRB have been ongoing in the past year to finalize the protocol. Local IRB approval for all HSRRB-recommended changes was received on 1 Apr 2004 and documentation was submitted to the HSRRB. The study will commence when HSRRB approval is received. No subjects have been enrolled and no study personnel have received salary support from the award.

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INTRODUCTION

The aim of the study is to determine whether a 1-year intensive resistance exercise training (RT) program is more effective than a moderate-intensity walking program in ameliorating the effects on body composition of androgen deprivation therapy (ADT). It is postulated that, in men on ADT for the treatment of locally advanced prostate cancer: 1) RT will attenuate the declines in bone mineral density (BMD) and fat-free mass (FFM) to a greater extent than walking; and 2) both RT and walking will prevent an increase in fat mass. A total of 40 men will be enrolled and randomized to either the RT or walking exercise programs. Primary outcomes are lumbar spine BMD and FFM. Secondary outcomes are: total body and hip BMD; fat mass; markers of bone turnover, to determine whether changes in BMD are the result of changes in bone resorption and/or formation; serum sex hormones, including testosterone, estradiol, estrone, and sex hormone binding globulin; physical functional performance; and quality of life. Local project support will enable additional assessments of risk factors for cardiovascular disease, including blood lipid profile, oral glucose tolerance, and arterial stiffness. These procedures were not included in the original grant application, but are described in the revised protocol that has been approved by the local IRB and submitted to the HSRRB for approval.

BODY

The first task in the Statement of Work is as follows:

Task 1: Preparation to initiate studies; months 1 – 3

- secure local IRB and HSRRB approval for study
- apply for research support from the General Clinical Research Center (GCRC)
- apply for research support from the Clinical Nutrition Research Unit (CNRU)
- prepare data forms
- prepare data base
- train research staff

The local IRB initially approved the protocol on 31 December 2002. Thereafter, repeated interactions with the Army HSRRB resulted in numerous modifications to the protocol. The HSRRB-recommended changes were approved by the local IRB on 1 April 2004. Final approval of the protocol by the HSRRB is pending. Task 2 of the Statement of Work (subject recruitment) will commence upon HSRRB approval of the protocol.

Applications for support of the project by institutional resources (GCRC, CNRU) have been submitted; approval is pending final approval of the protocol by the HSRRB.

The data forms and data base entry tables have been prepared. The research staff that will conduct the project will be experienced staff members that have worked on other research projects in the PI's lab. They are trained and ready to implement the protocol.

Because final HSRRB approval of the protocol has not been obtained, no subjects have been enrolled in the study. Study personnel have not yet received salary support from the award.

KEY RESEARCH ACCOMPLISHMENTS

Because the protocol has not yet been initiated, there are no key research accomplishments to date.

REPORTABLE OUTCOMES

none

CONCLUSIONS

none

REFERENCES

none

APPENDICES

none